UCLA Policy 916: Protocol Review and Approval by an Independent Scientific Review Committee For Clinical Trials– Public Review Draft

Issuing Officer:	Vice Chancellor for Research and Creative Activities
Responsible Department:	Office of Clinical Research
Effective Date:	TBD
Supersedes:	New

I. PURPOSE & SCOPE

The purpose of this Policy is to mandate protocol review and approval by an independent scientific review committee for studies that meet the NIH definition of a Clinical Trial. This review is intended to complement the Institutional Review Board (IRB) review with a detailed review of the required elements of the clinical protocol, statistical applications, adequate research staffing, any competing trials, well-constituted data collection forms, and utilization of other institutional resources.

This Policy applies to studies as defined by:

1. Principal Investigators within one of the Schools under the UCLA Health Sciences (Medicine, Nursing, Dentistry) OR
2. Any UCLA Principal Investigator whose study requires access to UCLA Health patients, resources, or services (for example UCLA health data, investigational pharmacy, laboratory medicine, imaging, clinical space, etc...). Please refer to online FAQ for more guidance.

II. DEFINITIONS

For the purposes of this Policy:

Clinical Trial as defined by the NIH, is a research study in which one or more human subjects are Prospectively Assigned to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial, to one or more Interventions (which may include placebo or other control) to evaluate the effects of those interventions on Health-Related Biomedical or Behavioral Outcomes. Please refer to NIH Clinical Trial Decision tool (https://grants.nih.gov/ct-decision/index.htm).

Health-Related Biomedical or Behavioral Outcomes as defined by the NIH, is the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Intervention as defined by the NIH, is a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Principal Investigator is defined in UCLA Policy 900.

Prospectively Assigned as defined by the NIH, is a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters)

Protocol is a document that can serve as an effective resource for communicating the science, methods, and operations of a Clinical Trial, to guide training and accountability of study staff, to allow for efficient review by peers and oversight bodies, to ensure adherence to the International Conference on Harmonisation (ICH) E6 Good Clinical Practice guidelines (https://ichgcp.net/6-clinical-trial-protocol-and-protocol-amendments), and to guide replication studies.

Responsible Party refers to the Principal Investigator or their designee for this Policy.

III. POLICY STATEMENT

A. All studies that meet the NIH Definition of a Clinical Trial will need a Protocol.

B. All studies that meet the NIH Definition of a Clinical Trial and one of the two requirements below are required to have review and approval by an independent scientific review committee

   1. Principal Investigators within one of the Schools under the UCLA Health Sciences (Medicine, Nursing, Dentistry) OR

   2. Any UCLA Principal Investigator whose study requires access to UCLA Health patients, resources, or services (for example UCLA health data, investigational pharmacy, laboratory medicine, imaging, clinical space, etc...). Please refer to online FAQ for more guidance

C. Protocol Review and Approval will occur as follows (see Attachment A: Scientific Protocol Review Policy Criteria and Workflow):

   1. For cancer Clinical Trials, the UCLA Internal Scientific Peer Review Committee (ISPRC) under the Jonsson Comprehensive Cancer Center will perform the review.

   2. For non-cancer Clinical Trials with documented external scientific review of the Protocol by a research sponsor or the FDA no additional review is needed unless:

      i. UCLA Health requires scientific review to access limited resources, services, and patient populations that require prioritization or assessment of feasibility.

      ii. The IRB may refer studies to one of the internal scientific peer review committees based on their review process.

   3. For non-cancer Clinical Trials without documented external scientific review, the UCLA campus has created an internal Scientific Review Committee (SRC) with staff support from the campus Clinical and Translational Science Institute that follows NIH's intramural standard (NIH standard).

IV. PROCEDURES

1. **Protocol Creation:** All studies that meet the NIH Definition of a Clinical Trial will need a Protocol. Protocol templates are available for both FDA regulated Clinical Trials as well as studies that include behavioral or social science interventions. Information and support for Protocol development can be found online (https://www.researchgo.ucla.edu/protocol-development). Also, see UCLA Policy 917: Good Clinical Practice Training for additional requirements.

2. **Protocol and Study Submission:** Electronic applications including a Protocol should be submitted through the UCLA IRB electronic submission system.
3. **Scientific Review Process:**
    a. Submissions that are marked as cancer-related will need review and approval from ISPRC prior to IRB approval. Please refer to the internal scientific peer review committee (ISPRC) under the Jonsson Comprehensive Cancer Center.
    b. Non-Oncology Clinical Trials for which there is external documented Protocol review (example: NIH, FDA, etc...). External review documents may be uploaded with the UCLA IRB electronic submission system. This will trigger an automatic exemption from the UCLA Health Independent Scientific Review process.
    c. Non-Oncology Clinical Trials without external documented Protocol review (example: NIH, FDA, etc...) will be routed to the internal scientific review committee after submission of an electronic IRB application. The IRB will reflect that the status of the application is in scientific review.
        i. The scientific review committee administrator will review study and manually exempt and release to the IRB studies that do not require review.
        ii. The study Protocol will be forwarded to reviewers and scheduled for scientific review committee with an initial review timeline goal of less than 2 weeks.
        iii. Scientific committee review outcomes include: approved (exempted); approved (no changes required); approved (minor changes recommended), not-approved (major changes required).
        iv. Any "approved" status will be recorded in the IRB electronic submission system and will result in the application immediately being routed to the IRB as a new submission.
        v. The scientific review committee will communicate the need for major changes to the Responsible Party. The Responsible Party should respond within thirty (30) days of the communication in order to initiate re-review. .
        vi. If the Responsible Party does not respond to a not-approved (major changes required) communication within thirty (30) days of the date of the communication, the study will be withdrawn from scientific review, unless the Responsible Party requests an extension to respond.

V. REFERENCES

1. UCLA Policy 900: Principal Investigator Eligibility
2. UCLA Policy 917: Good Clinical Practice Training
3. UCLA IRB Electronic Submission System

VI. ATTACHMENTS

A. Scientific Protocol Review Policy Criteria and Workflow

Issuing Officer

Vice Chancellor for Research and Creative Activities

Scientific (Protocol) Review Policy Criteria and Workflow